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10/672,891	09/26/2003	Jonathan S. Stinson	10527-450001/ 02-303	9546

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
ROE, JESSEE RANDALL	
ART UNIT	**PAPER NUMBER**
1742	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,891	STINSON, JONATHAN S.	
	Examiner	Art Unit	
	Jessee Roe	1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-21* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 March 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Status

Claims 1-6 and 8-21 are currently under examination wherein claims 1 and 18 are amended and claims 7 and 22-40 are canceled.

Status of Previous Rejections

The previous rejection of claims 1-9 and 15-20 under 35 U.S.C. 102(b) as being anticipated by Stinson et al. (US 5,888,201) is withdrawn in view of the Applicant's amendments to the claims. The previous rejection of claims 1-6, 13-14 and 22 under 35 U.S.C. 102(e) as being anticipated by Mayer (US Publication 2003/0009215) is withdrawn in view of the Applicant's amendments to the claims. The previous rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (JP 11-042283) in view of Steinemann et al. (US 4,040,129) is withdrawn in view of the Applicant's amendments to the claims. The previous rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (JP 11-042283) in view of "Thermomechanical Analysis of Ti40Ta and Ti50Ta Alloys" is withdrawn in view of the Applicant's amendments to the claims. The previous rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (JP 11-042283) in view of Kim (US 6,146,404) is withdrawn in view of the Applicant's amendments to the claims.

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 recites "...wherein the alloy includes 20 weight percent or greater of Zr, Ta, Mo or a combination thereof". However, claim 8 recites "wherein the alloy includes 80 weight percent or less of Zr, Ta or Mo or a combination thereof", wherein the lower limit of this would be 0 weight percent of Zr, Ta or Mo, thereby failing to further limit claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-10, 12-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinemann et al. (US 4,040,129) in view of Draenert (US 5,047,030).

In regards to claims 1, 6, 9-10, and 12-15, Steinemann et al. ('129) disclose a corrosion resistant alloy that would be used as screws fixed in bones (col. 2, lines 27-46 and col. 4, line 51 – col. 5, line 9) comprising from 3-30 weight percent consisting of one

or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being either titanium or zirconium (col. 3, lines 47-58). However, Steinemann et al. ('129) do not specify wherein the screws would be tubular.

Draenert ('030) discloses wherein the titanium alloy screws that would be fixed into bones would be tubular (col. 3, lines 29-41).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the screws that would be fixed in bones, as disclosed by Steinemann et al. ('129), into a tubular shape, as disclosed by Draenert ('030), because Draenert ('030) discloses tubular screw titanium alloys would be suitable for screwing into bones (col. 3, lines 29-41).

Still regarding claims 1, 6, 9-10 and 12-15, the Examiner notes that the composition of the alloy disclosed by Steinemann et al. ('129) overlaps the composition of the alloy of the instant invention, which is a prima facie case of obviousness. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the desired amounts of molybdenum, zirconium, tantalum and titanium from the compositions disclosed by Steinemann et al. ('129) because Steinemann et al. ('129) disclose the same utility (biocompatible alloys) throughout the disclosed ranges.

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more of claim 1, the Examiner asserts that these properties would be met

by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

Still regarding claim 1, the recitation "a balloon-expandable medical stent" has been considered as a property limitation, but because Steinemann et al. ('129) disclose an alloy with a composition that is substantially similar to the composition of the instant invention, it would be expected that the alloy of Steinemann et al. ('129) would also be capable of being "balloon expandable" as claimed. See MPEP 2112.01 I.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of a titanium and zirconium and/tantalum alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and a percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitation that the alloy have a mass absorption coefficient of about 2.9 cm^2/g or less of claim 5, the Examiner asserts that these properties would be

met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to claims 19-20, Draenert ('030) discloses wherein the diameter (thickness) of a tubular shaped titanium alloy would be 0.6 to 1.0 mm (about 0.024 in – 0.39 in) when used as a drug delivery system (carrying a therapeutic agent), which does not overlap but is on the same order of magnitude (about 0.0015 inch to about 0.015 inch) as that of the instant invention. However, merely changing the size of the tube (screw) would not be sufficient to patentably distinguish over the prior art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

Claims 1-6, 9, 11-12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,685,306).

In regards to claims 1, 9, 11-12, and 14-15, Davidson ('306) disclose low modulus, corrosion resistant titanium alloys having (I) titanium; about 10-20 weight percent niobium; and from about 0-20 weight percent zirconium; and (II) titanium; about 35-50 weight percent niobium; and from about 0-20 weight percent zirconium (abstract

and col. 4, lines 32-40). Tantalum may be used as a substitute for niobium (col. 4, lines 32-40). The alloy would be tubular in shape (Fig. 10 and col. 13, lines 17-28). The Examiner notes that the composition of the alloy disclosed by Davidson ('306) overlaps the composition of the alloy of the instant invention, which is a prima facie case of obviousness. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the desired amounts of zirconium, tantalum and titanium from the compositions disclosed by Davidson ('306) because Davidson ('306) disclose the same utility (biocompatible alloys) throughout the disclosed ranges.

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more of claim 1, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

Still regarding claim 1, the recitation "a balloon-expandable medical stent" has been considered as a property limitation, but because Davidson ('306) disclose an alloy with a composition that is substantially similar to the composition of the instant invention, it would be expected that the alloy of Davidson ('306) would also be capable of being "balloon expandable" as claimed. See MPEP 2112.01 I.

Still regarding claim 14, Davidson ('306) do not specify wherein molybdenum would exceed 20 weight percent within the alloy, therefore the alloy of Davidson ('306) satisfied the limitation of having 20 weight percent or less.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and a percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

In regards to the limitation that the alloy have a mass absorption coefficient of about 2.9 cm^2/g or less of claim 5, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. See MPEP 2112.01 I.

Claim 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,685,306) as applied to claim 1 above, and further in view of The ASM Handbook Volume 2.

In regards to claim 16, Davidson ('306) discloses using titanium as part of a biocompatible alloy as shown above, but Davidson ('306) does not specify wherein the titanium would be commercially pure titanium.

The ASM Handbook Volume 2 discloses where commercially pure titanium would be used in applications where high strength is not a requirement and corrosion resistance is important (pg. 588, col. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use commercially pure titanium, as disclosed by the ASM Handbook Volume 2, as the titanium component in the biocompatible, corrosion resistant titanium alloys, as disclosed by Davidson ('306), because commercially pure titanium would be used for corrosion applications, as disclosed by the ASM Handbook Volume 2 (pg. 588, col. 3).

Claim 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinemann et al. (US 4,040,129) in view of Draenert (US 5,047,030) and further in view of The ASM Handbook Volume 2.

In regards to claim 16, Steinemann et al. ('129) in view of Draenert ('030) disclose using titanium as part of a biocompatible alloy as shown above, but neither Steinemann et al. ('129) nor Draenert ('030) specify wherein the titanium would be commercially pure titanium.

The ASM Handbook Volume 2 discloses where commercially pure titanium would be used in applications where high strength is not a requirement and corrosion resistance is important (pg. 588, col. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use commercially pure titanium, as disclosed by the ASM Handbook Volume 2, as the titanium component in the biocompatible, corrosion resistant titanium alloys, as disclosed by Steinemann et al. ('129) with evidence from Draenert ('030), because commercially pure titanium would be used for corrosion applications, as disclosed by the ASM Handbook Volume 2 (pg. 588, col. 3).

In regards to claim 17, Steinemann et al. ('129) disclose 3-30 weight percent molybdenum (col. 3, lines 47-58).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,685,306) as applied to claim 1 above, with evidence from Wiktor (US 5,653,727).

In regards to claim 21, Davidson ('306) discloses a catheter and a stent that would be expanded by a balloon expandable catheter wherein both the stent and the catheter would be made of low modulus, corrosion resistant titanium alloys having (I) titanium; about 10-20 weight percent niobium; and from about 0-20 weight percent zirconium; and (II) titanium; about 35-50 weight percent niobium; and from about 0-20 weight percent zirconium (abstract, col. 4, lines 32-40 and col. 12, line 65 – col. 13, line 15), wherein tantalum may be used as a substitute for niobium (col. 4, lines 32-40). However, Davidson ('306) do not specify wherein the balloon would have a maximum diameter of about 1.5 mm to about 14 mm.

Wiktor ('727) discloses using balloons catheters that have 10 mm and 12 mm diameters to expand a titanium stent (col. 6, lines 28-52). Therefore, it would be

expected that the size of the balloon catheter of Davidson ('306) would be similar to the size of the balloon of Wiktor ('727) because both Davidson ('306) and Wiktor ('727) disclose a substantially similar system wherein a stent would be expanded by a balloon catheter and because both have the same intended use.

Response to Arguments

Applicant's arguments with respect to claim 1-6 and 8-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Roy V. King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JR

ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700